

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in February 2015.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-406

Trade Name: NexGard®
Ingredients: Afoxolaner
Sponsor: Merial, Inc.
Approval Date: February 23, 2015

The effect of the supplement is to provide for the treatment and control of Brown dog tick (*Rhipicephalus sanguineus*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for one month.

ANADA Number: 200-146

Trade Name: Tetroxy 25®
Ingredients: Oxytetracycline HCl
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: February 24, 2015

This supplement provides for a change in the proprietary name from Oxytetracycline HCl Soluble Powder to Tetroxy 25®, the removal of the residue warning statement for pre-ruminating and veal calves from the labeling and the addition of a new species (honey bees) and the corresponding indications. Tetroxy 25® is indicated for the control of American Foulbrood caused by *Paenibacillus larvae* and European Foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

Sponsor Change

NADA Numbers: 141-084, 141-204, 141-333

Previous: Novartis Animal Health US, Inc.
New Sponsor: Virbac AH, Inc.
Drug Labeler Code: 051311

(A)NADA Numbers: 200-070, 141-098, 141-103, 141-346, 141-434

Previous: Abbott Laboratories
New Sponsor: Zoetis Inc.
Drug Labeler Code: 054771

ANADA Number: 200-197

Previous: Contemporary Products, Inc.
New Sponsor: Huvepharma AD
Drug Labeler Code: 016592

NADA Number: 141-435

Previous: Piedmont Animal Health

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New Sponsor: Bayer HealthCare LLC, Animal Health Division

Drug Labeler Code: 000859